Application No.: 10/556,931

Office Action Dated: June 18, 2008

PATENT REPLY FILED UNDER EXPEDITED PROCEDURE PURSUANT TO 37 CFR § 1.116

REMARKS

Claims 1, 4, 6, and 14 have been amended. Claims 1, 4, 6, and 14 have been amended to delete the term "radical." The Applicants have further considered the Office's October 22, 2007 restriction requirement. Further to the remarks regarding that restriction in their November 15, 2007 Response, the Applicants request further consideration. The office has accepted the Applicants' proposed restriction, as follows:

- Group I: Claims 1-6 and 8, drawn to compounds and compositions of Formula I, wherein Z^1 - Z^2 = -O-CH₂-O- (b-1).
- Group II: Claims 1-6 and 8, drawn to compounds and compositions of Formula I, wherein $Z^1-Z^2 = -O-CH_2-CH_2-O-$ (b-2).
- Group III: Claims 1-6 and 8, drawn to compounds and compositions of Formula I, wherein $Z^1-Z^2 = -NR^7-CH_2-CH_2-O-$ (b-3).
- Group IV: Claims 1 and 8, drawn to compounds and compositions of Formula I, wherein $Z^1-Z^2 = -O-CH_2-CH_2-NR^7-$ (b-4).
- Group V: Claims 1 and 8, drawn to compounds and compositions of Formula I, wherein $Z^1-Z^2 = -NR^7-CH_2-CH_2-NR^7-$ (b-5).
- Group VI: Claims 1 and 8, drawn to compounds and compositions of Formula I, wherein Z^1 - Z^2 = -S-CH₂-CH₂-O- (b-6).
- Group VII: Claims 9-13, drawn to methods of prevention and/or treatment of diseases or disorders using a compound of Groups I-VI.
- Group VIII: Claims 14-20, directed to processes for the preparation of compounds of Formula I.

In light of the homology present in certain of the identified groups, consolidation of Groups I and II and Groups III and IV is requested. The revised restriction is as follows:

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- Group I: Claims 1-6 and 8, drawn to compounds and compositions of Formula I, wherein Z^1 - Z^2 = -O-CH₂-O- (b-1) and wherein Z^1 - Z^2 = -O-CH₂-CH₂-O- (b-2).
- Group II: Claims 1-6 and 8, drawn to compounds and compositions of Formula I, wherein $Z^1-Z^2 = -NR^7-CH_2-CH_2-O-$ (b-3) and wherein $Z^1-Z^2 = -O-$ CH₂-CH₂-NR⁷- (b-4).
- Group III: Claims 1 and 8, drawn to compounds and compositions of Formula I, wherein $Z^1-Z^2 = -NR^7-CH_2-CH_2-NR^7-$ (b-5).
- Group IV: Claims 1 and 8, drawn to compounds and compositions of Formula I, wherein Z^1 - Z^2 = -S-CH₂-CH₂-O- (b-6).
- Group V: Claims 9-13, drawn to methods of prevention and/or treatment of diseases or disorders using a compound of Groups I-IV.
- Group VI: Claims 14-20, directed to processes for the preparation of compounds of Formula I.

Claims 1 and 14 have been amended in accordance with Group I.

The Applicants request entry of the present amendment under 37 C.F.R § 1.116(b) because the amendments to the claims either comply with requirements expressly set forth in a previous Office Action or present the rejected claims n better form for consideration on appeal.

Claim for foreign priority under 35 U.S.C. § 119

The Applicants note that the Examiner has not acknowledged the Applicants' claim for foreign priority under 35 U.S.C. § 119. A request for acknowledgement was made in the Response filed February 25, 2008. In the preliminary amendment filed with the application on November 16, 2005, the Applicants identified that the present application is the national stage of PCT/EP2004/050922, filed May 26, 2004, which claims priority from PCT/EP03/05789, filed May 30, 2003. Certified copies of these documents should have been

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forwarded by the International Bureau. The Applicants respectfully request that the claim for foreign priority be acknowledged.

Rejections under 35 U.S.C. § 112

The Office has maintained the rejection of claims 1-9 regarding the scope of enablement for R¹-R⁶, R⁸, Y, and X, alleging that "the full scope of the terms alkyl alkenyl, aryl, and heteroaryl have not been overcome in view of Applicants amending the claims." Action at 2-3. As previously amended, and as currently pending, each R¹, R², R³, R⁴ and R⁶ is independently hydrogen, halo, cyano, nitro, hydroxy, R⁵ is hydrogen or alkyl, R⁸ is hydrogen, X is CR⁶, and Y is (c-1) or (c-2). The definition of the term "alkyl" is explicitly presented in the claims. Definitions of alkenyl, aryl and heteroaryl have been deleted, as these terms are no longer present. Withdrawn of the rejection is requested.

The Office has also maintained the rejection of claims 1-9 regarding the use of the term "radical." The Applicants continue to disagree with the Office's position and maintain that one skilled in the art would readily be able to ascertain the scope of the invention in light of the ordinary meaning of the term. Nevertheless, the claims have been amended to remove the term "radical." Withdrawal of the rejection is requested.

Rejection under 35 U.S.C. § 103

The claims stand rejected under 35 U.S.C. § 103 as allegedly obvious over WO02/085911 (Tran). The Applicants disagree and request reconsideration and withdrawal of the rejection.

The compounds of the claimed invention, which expressly exclude the compounds set forth in Tran, exhibit a higher dopamine D₂ and/or D₃ and/or D₄ antagonist activity combined with a higher selective seratonin reuptake inhibition and/or 5HT_{1A} activity compared to the compounds of the prior art. *See* Specification at page 34, lines 31-33 and Table 2. Moreover, the compounds of the invention act as 5-HT_{1A} agonists or partial agonists. *Id.* at page 14, lines, 25-30. In contrast, the compounds described in Tran are seratonin reuptake inhibitors/5-HT_{1A} antagonists that have no described dopamine antagonist activity. Tran at page 12, lines 1-12. As a result, one skilled in the art would not have been motivated to modify the compounds of Tran to produce the *dopamine antagonists*/5-HT_{1A} agonists of the

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present invention. The invention is non-obvious of the cited art and the Applicants respectfully request withdrawal of the rejection.

* * *

The Applicants assert that the foregoing constitutes a full and complete response to the pending Office Action and that the claims are in condition for allowance. An early notice to that effect is, therefore, earnestly solicited.

Date: August 18, 2008 /Stephanie A. Barbosa/

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